## Badylak Case Study

# TISSUE REGENERATION/REGROWTH

Pioneers in the arena of tissue regrowth, Dr. Stephen Badylak at Purdue University and Dr. Alan Spievack at Harvard University were both researching and using the application of a composition known as extracellular matrix (ECM). Their research involved similar, but not identical processes. Dr. Badylak's work centered on human tissue regeneration, while Dr. Spievack's interests were in the veterinary arena, specifically for regenerating tissue in cases of skin wounds and surgery.

Dr. Badylak was abruptly dismissed by Purdue University, where he had taught and researched for over 25 years. Based on similarities between their work, the Purdue Research Foundation and Cook Biotech, a licensee of Purdue, sued Dr. Badylak, Dr. Spievack and ACell, a company founded by Spievack, accusing them of patent infringement. Purdue also sought to impede Dr. Spievack's patent applications based on his work by demanding that the U.S. Patent and Trademark Office add Dr. Badylak and four other Purdue researchers to Spievack's patents.

### DISPUTE OVERVIEW

Prior to the filing of the Purdue patent in question, Dr. Spievack met Dr. Badylak at a conference where Badylak made a presentation on submucosa of the small intestine (SIS). Shortly thereafter, Dr. Spievack began experiments working with bladder tissue and successfully treated a poison ivy outbreak on his own leg with a composition derived from that same bladder wall. Later, the courts found that this is the point in time that Dr. Spievack completed his invention.

Subsequently, Dr. Spievack shared the results of his work with Dr. Badylak, but only after Dr. Badylak filed for the Purdue patent. Then they maintained regular communication about Dr. Spievack's research. Dr. Spievack tried to acquire licensure from Purdue strictly for work on the non-SIS products that had been developed. When he was rejected, he continued with his own research, concentrating on urinary bladder matrix (UBM).

Three years later, Purdue dismissed Dr. Badylak and filed suit against him, Dr. Spievack and ACell. No damages were awarded, and ultimately, the courts found that there had been no patent infringement, but at what cost to the inventors, their research efforts, the University reputation and the public overall?

## Resolution

This case study highlights the seemingly opposing interests of the public good and the profitability of research. In this case, the researchers took care to share their work without infringing upon one another's patents, but commercial interests provoked a lawsuit nonetheless.

While appealing the initial decision, ACell was forced to cease operations for eighteen months. How much life-saving research could have been conducted during this time? How many lives might have otherwise been saved?

Purdue University lost a valuable researcher. Dr. Badylak moved on to become a successful research professor in the Department of Surgery and serves as Director of Tissue Engineering at the McGowan Institute for Regenerative Medicine at the University of Pittsburgh.

Dr. Spievack passed away on March 15, 2008 at his home in Cambridge, at age 74, after a long struggle with cancer.

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## Innovation And Patent Details

In all of the research and application by both doctors, the ECM (extracellular matrix) compositions in question act as a scaffold upon which new tissue forms to replace damaged or lost tissue. During the tissue regrowth process, the ECM is completely degraded and replaced with new tissue growth. This manner of treatment has been used successfully on both humans and animals.

### INSTITUTION WHERE INVENTION/INNOVATION WAS DEVELOPED

Purdue University

### NAME OF INVENTOR/INNOVATOR – TITLE – ADVANCED DEGREES HELD

Dr. Stephen R. Badylak, D.V.M., Ph.D., M.D.

### PATENT NUMBERS, DATES ISSUED, PATENT HOLDER'S NAME

***Purdue Patent***

**PATENT 5,554,389:** Urinary bladder submucosa derived tissue graft; a tissue graft composition comprising bladder submucosal tissue delaminated from abluminal muscle layers and at least the luminal portion of the tunica mucosa of a segment of vertebrate urinary bladder is described. The graft composition can be implanted to replace or support damaged or diseased tissues.

**Filed:** September 10, 1996
**Inventors:** Dr. Stephen R. Badylak, Dr. Sherry L. Voytik, Dr. Andrew Brightman, Dr. Matt Waninger
**Assignee:** Purdue Research Foundation

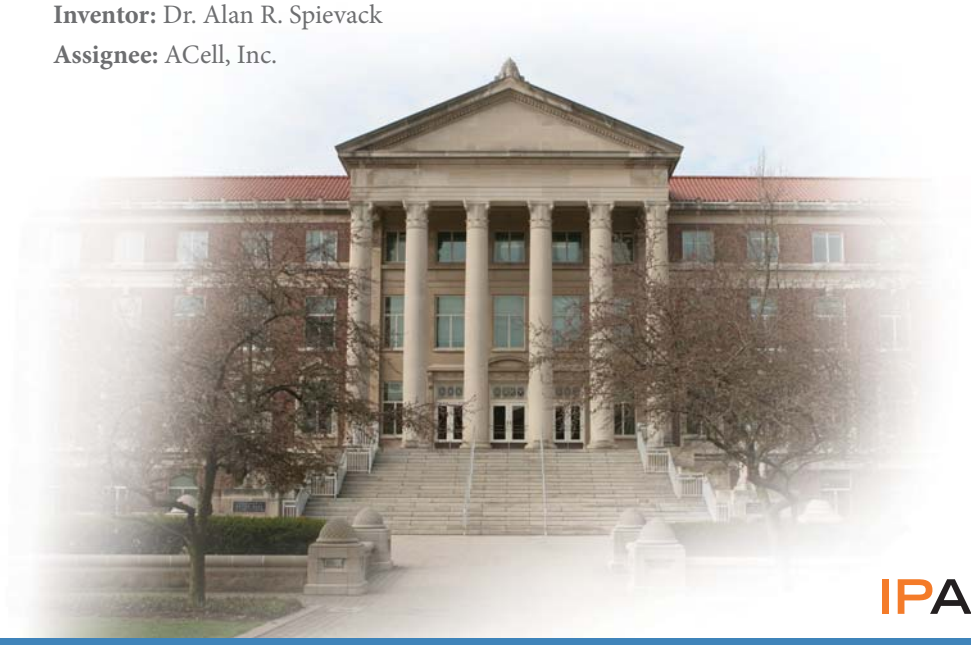
***ACell Patents***

**PATENT 6,576,265:** Tissue regenerative composition, method of making, and method of use thereof; a matrix, including epithelial basement membrane, for inducing repair of mammalian tissue defects and in vitro cell propagation derived from epithelial tissues of a warm-blooded vertebrate.

**Filed:** October 18, 2000
**Inventor:** Dr. Alan R. Spievack
**Assignee:** ACell, Inc.
**Commercial Name:** ACell Vet™

**PATENT 6,579,538:** Tissue regenerative compositions for cardiac applications, method of making, and method of use thereof; a matrix, including epithelial basement membrane, for inducing repair of mammalian tissue defects and in vitro cell propagation derived from epithelial tissues of a warm-blooded vertebrate.

**Filed:** October 18, 2000
**Inventor:** Dr. Alan R. Spievack
**Assignee:** ACell, Inc.



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Dr. Stephen Badylak, a 25-year veteran professor and researcher of Purdue University, discovered in the mid-1980s that certain types of tissues could be used as a "scaffold" for other tissues to build upon for purposes of tissue regeneration. These scaffold tissues became known as extracellular matrices ("ECMs") and were sourced from the submucosa of the small intestine ("SIS"), stomach, liver basement and urinary bladder ("UBS") as well as the urinary bladder matrix ("UBM"). This was coined the "389" patent in the ensuing lawsuits. The UBS and UBM tissues were the subjects of the controversy that is the core of this case study.

## Dispute Details

Dr. Alan Spievack, a surgeon and Harvard University professor, had been interested in the possibility of regenerative capabilities of epithelial (skin or mucous membrane tissues) basement membranes since the 1950s after his work with salamanders' ability to regenerate limbs garnered him a Fulbright Scholarship. Dr. Spievack met Dr. Badylak in early 1996, prior to the filing of the Purdue patent in question, at a conference where Badylak made a presentation on SIS (submucosa of the small intestine). Beginning in March of 1996, Dr. Spievack began experiments working with tissue extracted from the bladder wall and in July of that same year, he successfully treated a poison ivy outbreak on his own leg with a composition derived from that same bladder wall.

Dr. Spievack shared the results of his work with Dr. Badylak, but not until after October, 1996, subsequent to the filing of the "389" patent based on Dr. Badylak's research. From the end of 1996 and for the next three years, Dr. Spievack visited Dr. Badylak at Purdue and discussed with him the work he was conducting with graft compositions. In 1998, Dr. Spievack tried to acquire licensure from Purdue to the "389" patent strictly for work on the non-SIS products that had been developed. When he was rejected, he continued with his own research, concentrating on UBM.

The district court in the Cook Biotech/Purdue initiated lawsuit ruled that Spievack had completed the invention covered in the "265" patent when he successfully treated his own poison ivy outbreak in the summer of 1996, prior to the time he met and began conversing with Dr. Badylak on their shared interests.

### UNIVERSITY INVOLVEMENT

As a result of his work, Dr. Spievack filed two patent applications in October 2000 which were issued in June 2003 - the "265" and "538" patents. During the patent approval process, Purdue Research Foundation ("PRF"), under the auspices of 37 C.F.R. § 1.47(a), demanded that Dr. Badylak and four other Purdue researchers be added as co-inventors to Spievack's patents. Dr. Badylak filed papers under oath denying any inventorship in Spievack's patents. The U.S. Patent and Trademark Office denied Purdue's request to add additional inventors to Spievack's patents.

### LEGAL FILINGS/PROCEEDINGS

Cook Biotech Incorporated and Purdue Research Foundation v. ACell, Incorporated, Stephen F. Badylak and Alan R. Spievack

Counter Claim by ACell Incorporated, Badylak and Spievack v. Cook Biotech and Purdue

**Plaintiff Assertions:** Patent Infringement
**Damages Sought:** $1,815,700
**Filed:** June 23, 2003

### AWARDS/LEGAL RULINGS

**DECISION:** A jury found that ACell and the other defendants were infringing upon the patent of Cook Biotech, but did not find that they were doing so willfully. The plaintiffs, though victorious in this initial suit, were awarded no damages.

**APPEAL:** A panel of three judges of the Federal Circuit Court of Appeals unanimously reversed the decision on the basis that the Federal District Court misinterpreted the scope of the patent held by Purdue that the defendants were accused of infringing.

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## Analysis

### IMPLICATIONS OF CASE

There are two major implications in this case which are important to the university researcher: (1) the notion that discussing research with other researchers is illicit; and (2) the damage to the health and well being of the public through prolonged litigation of a life-saving and/or life-altering treatment.

Prior to the passage of the Bayh-Dole Act, academic research was a process of cumulative work. Scientists built on the work of other scientists and mankind benefited. Publication of research results was the accepted standard and the research community was just that - a community - one that shared its work and collaborated for the greater good.

However, in the present Bayh-Dole era, secrecy is encouraged in order to protect the potential profitability of innovations. Universities, now operating in the business arena, have become savvy to the revenue producing aspects of the work of their researchers.

Still, it is the nature of the academic researcher, as it should be, to cooperate and impart knowledge where it can do the most good, not in terms of dollars and cents, but for the greatest benefit to society.

That society, in fact, is the major provider of funds to support research. Nevertheless, it may not be accorded the full measure of the potential of the investigations it finances due to the secrecy and confidentiality strictures placed on academicians in this age of patents for profit.

To the second point of discussion, ACell was forced to shut down operations from July 2005 through November 2006 while the company appealed the lower court decision that ACell had infringed patents that were owned by Purdue Research Foundation and licensed to Cook Biotech.

The Federal Court of Appeals unanimously overturned the lower court ruling in August 2006 and operations resumed shortly thereafter.

The question remains, during the 18 month hiatus necessitated by the Cook Biotech/Purdue litigation, what progress in the field of tissue regeneration was postponed? How many lives, both human and veterinary could have been bettered?

Dr. Spievack passed away on March 15, 2008 at his home in Cambridge after a long struggle with cancer. He was 74 years old.

### FUTURE ACTIVITY ANTICIPATED

Purdue and Cook Biotech were denied a Petition for Rehearing by the Federal Circuit of Appeals Court who had overturned their prior victory over the inventors, leaving the Supreme Court as their only venue for another appeal. While Purdue has accepted the court's verdict and moved on, Cook Biotech vows to take back rights from the inventors of the life-changing technology.

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